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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,005	06/30/2003	Rong-Ming Lyu	LYUR3001/REF	1970

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/608,005

**Applicant(s)**

LYU ET AL.

**Examiner**

Christopher R. Tate

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-20 are presented for examination on the merits.

#### ***Specification***

The disclosure is objected to because of the following informalities:

On page 2, in the second full paragraph, reference is made to the teachings of U.S. Application No. 09/949,610. Applicants should instead refer to the U.S. Patent which issued therefrom - i.e., U.S. Patent No. 6503542. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-13, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9, and 15 are rendered vague and indefinite because they fail to recite any operative amounts and/or ratios of the claimed herbal extracts. Therefore, it is unclear if each of the extracts is an active agent within the composition, if it is merely some type of inert agent, and/or if it is present in very small amounts representing perhaps a contaminant or residue. The claimed herbal extracts are deemed to be essential elements of the invention and, as such, should be clearly defined in the claim language itself. Accordingly, it is suggested that the limitations of claims 7, 14, and 20 be appropriately incorporated in claims 1, 9, and 15, respectively.

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Claims 2 and 3 are rendered vague and indefinite by the awkward and confusing phrase "extracted through an alcohol". For clarity, it is suggested that this phrase be amended to recite the more conventional phrasing --extracted with an alcohol--.

Claims 2, 13, 15, and 19 are rendered vague and indefinite by the ranges beginning with "0% to" because it is unclear how the herbals could be extracted with an alcohol if the extraction solvent contains 0% alcohol.

Claims 9 recites the limitation "the extracts" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the alcohol range of "0% to 90% which is outside the limitations of claim 9 from which it depends which is confusing, unclear and improper - i.e., claim 9 recites an alcohol range of "40% to 95%".

Claims 15 recites the limitation "the alcohol extracts" in line 2. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Huo et al. (US 6,093,403).

A pharmaceutical composition comprising extracts of *Radix Dioscorea*, *Rhizoma Alismatis*, *Poria cocos*, and *Scutellaria Baicalensis* is claimed. Dependent claims include the extracts being prepared with a solvent containing 0-95% alcohol, and the composition further comprising an excipient.

Huo et al. teach a pharmaceutical composition comprising *Rhizoma Dioscorea* (please note that it is well recognized in the herbal art that rhizomes are part of the plant roots and, thus, read upon *Radix Dioscorea*), *Rhizoma Alismatis*, *Poria cocos*, and *Scutellaria Baicalensis*. Hou et al. further teach that the extracts are preferably prepared via hot water extraction (water contains 0% alcohol), and mixing the herbal pharmaceutical composition with food (which reads upon an excipient). See, e.g., col 3, line 7 - col 7, line 22, and claims.

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huo et al. (US 6,093,403), Liang et al. (US 2002/0031559), or Chen (US 2004/0105902), in view of Chang (US 5,503,810).

Huo et al. teach a pharmaceutical composition comprising Rhizoma *Dioscorea* (please note that it is well recognized in the herbal art that rhizomes are part of the plant roots and, thus, read upon Radix *Dioscorea*), Rhizoma *Alismatis*, *Poria cocos*, and *Scutellaria Baicalensis*. Hou et al. further teach that the extracts are preferably prepared via water extraction (water contains 0% alcohol), and mixing the herbal pharmaceutical composition with food (which reads upon an excipient). Hou et al. also beneficially teach preferred compositions that contain the instantly claimed herbal extracts in weight ranges that encompass the instantly claimed weight ratios; and that the herbal constituents may be prepared a number of different ways other than hot water extraction (see, e.g., col 3, line 7 - col 7, line 22, and claims).

Liang et al. teach pharmaceutical compositions (including anti-asthmatic and/or anti-allergic compositions) comprising one or more excipients and a mixture of concentrated herbal extracts that may beneficially contain each of the herbals instantly claimed - i.e., *Dioscorea* (Bi Xie) and/or *Dioscorea batata* (Shan Yao), *Alismatis* (Ze Xie), *Poria cocos* (Fu-ling), and *Scutellaria baicalensis* (Huang Qin) - therein, for their disclosed medicinal advantages. Liang et al. further teach that common, classical ways to prepare Oriental herbal medicines is to extract selected herbs with water or other solvents such as alcohol; and that their concentrated herbal extracts can be obtained via conventional methods such as disclosed by Chang - which include hot water and/or alcoholic extraction (see, e.g., Chang - col 1, lines 52-60 and col 3, lines 29-38). See, e.g., Liang et al. - paragraphs [0007], [0012], [0016] - [0043], [0050] - 0068], and claims.

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Please note that it is well recognized in the Chinese herbal art that the conventional parts of such medicinal herbals typically include the roots and rhizomes. Thus, although silent with respect to extracting the particular part(s) of such herbals, using the root and/or rhizome of such Chinese herbs in preparing the medicinal herbal extracts taught by Liang et al. would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Chen teaches a pharmaceutical composition comprising one or more excipients and which may beneficially comprise each of the herbal extract components instantly claimed - i.e., *Rhizoma Dioscorea* (Bei Xie - please note that it is well recognized in the herbal art that rhizomes are part of the plant roots and, thus, read upon *Radix Dioscorea*), *Rhizoma Alismatis*, *Poria cocos*, and *Scutellaria radix* (Huang On - *Scutellaria Baicalensis*). Chen also advantageously discloses that the extracts can be obtained via water extraction and/or using other conventionally employed extraction solvent (see, e.g., paragraphs [0014] - 0020], [0026] - 0030], Example 1, and claims).

Based upon the beneficial teachings provided by the cited references with respect to medicinal herbal compositions comprising each of the bioactive herbal components instantly claimed - as discussed above, the adjustment of particular conventional working conditions (e.g. extracting such Chinese herbals using a particular conventional extraction solvent such as aqueous alcohol/aqueous ethanol, and/or determining appropriate amounts and/or ratios of such herbal extracts within a particular pharmaceutical vehicle), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of each of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to the art rejections above, it is noted that the cited references do not necessarily teach that their composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent to each of the reference compositions (see, e.g., MPEP 2112).

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Christopher R. Tate', with a stylized flourish at the end.

Christopher R. Tate  
Primary Examiner  
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